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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,451	11/28/2003	Joel Bougaret	3493-0126P	9996

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,451	BOUGARET ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 (in part), 3-6, 18-19 (in part) and 32-34, drawn to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, lubricant, colloidal silica, and lactose in which the idazoxan is the polymorph of form I, classified in class 514, subclasses 402 and 454.

II. Claims 1-2 (in part), 18-19 (in part) and 35-36, drawn to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, lubricant, colloidal silica, and lactose in which the idazoxan is the polymorph of form II, classified in class 514, subclasses 402 and 454.

III. Claims 1-2 (in part), 7-9, 18-19 (in part), 37-38, drawn to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, lubricant, colloidal silica, and lactose in which the idazoxan is the polymorph of form III, classified in class 514, subclasses 402 and 454.

IV. Claims 1-2 (in part), 10-13, 18-19 (in part), and 39-41, drawn to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, lubricant, colloidal silica, and lactose in which the idazoxan is the polymorph of form IV, classified in class 514, subclasses 402 and 454.

V. Claims 1-2 (in part), 14-17, 18-19 (in part), 42-43, drawn to a pharmaceutical composition comprising idazoxan salt, microcrystalline

cellulose, lubricant, colloidal silica, and lactose in which the idazoxan is the polymorph of form V, classified in class 514, subclasses 402 and 454.

VI. Claims 20-23, drawn to tablets comprising the pharmaceutical composition of claim 1, classified in class 514, subclasses 402 and 454 and class 424, subclass 464.

VII. Claims 24-28, drawn to a process for the manufacture of a tablet comprising a stage of direct tableting of a powder mixture, classified in class 514, subclasses 402 and 454 and class 424, subclass 464.

VIII. Claims 29-30, drawn to use of a composition or a tablet intended for the preventive and/or curative treatment of a pathology selected from the group consisting of depression, Parkinson's disease and severe psychotic disorders, classified in class 514, subclasses 402 and 454.

The inventions are distinct, each from the other because of the following reasons:

Any of Inventions I, II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different polymorphs of idazoxan that are characterized by different X-ray diffraction spectrums. Because these inventions are distinct for the reasons given above and the search required for any of Inventions I, II, III, IV, or V is not required for any of the other Inventions, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search

burden to be searched together. Thus, Groups I, II, III, IV, and V have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Any of Inventions I, II, III, IV and V are unrelated to Invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, a lubricant, colloidal silica, and lactose in which the idazoxan has different polymorphs characterized by X-ray diffraction spectrums and to tablets comprising the pharmaceutical composition of Inventions I-V. Because these inventions are distinct for the reasons given above and the search required for any of Inventions I, II, III, IV, or V is not required for Invention VI, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Groups I, II, III, IV, and V have been appropriately restricted from Group VI on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I, II, III, IV and V are unrelated to Invention VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to a pharmaceutical composition comprising idazoxan salt, microcrystalline cellulose, a lubricant, colloidal

silica, and lactose in which the idazoxan has different polymorphs characterized by X-ray diffraction spectrums and to a process for the manufacture of a tablet. Because these inventions are distinct for the reasons given above and the search required for any of Inventions I, II, III, IV, or V is not required for Invention VII, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Groups I, II, III, IV, and V have been appropriately restricted from Group VII on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions I, II, III, IV and V are related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the use of an idazoxan composition as a medicament for the treatment of depression, Parkinson's disease, or psychotic disorders can be accomplished with another materially different product, such as tricyclic antidepressants, L-DOPA, and clozapine, respectively. Because these inventions are distinct for the reasons given above and the search required for any of Inventions I, II, III, IV, or V is not required for Invention VIII, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap

thus presenting a search burden to be searched together. Thus, Groups I, II, III, IV, and V have been appropriately restricted from Group VIII on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions VI and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process for the manufacture of a tablet comprised of the pharmaceutical composition of Invention I can be used to make another and materially different product, such as pharmaceutical compositions with different active ingredients. Because these inventions are distinct for the reasons given above and the search required for Invention VI is not required for Invention VII, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group VI has been appropriately restricted from Group VII on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the tablets comprising the pharmaceutical composition of Invention I as a medicament intended for the preventive and/or curative treatment of a pathology selected from the group consisting of depression, Parkinson's disease and psychotic disorders, can be practiced with another materially different product, such as tricyclic antidepressants, L-DOPA or clozapine, respectively. Because these inventions are distinct for the reasons given above and the search required for Invention VI is not required for Invention VIII, restriction for examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group VI has been appropriately restricted from Group VIII on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to a process for the manufacture of a tablet, comprising a stage of direct tableting of a powder mixture and to the use of the pharmaceutical composition or tablet of Group I for the preventive and/or curative treatment of a pathology selected from the group consisting of depression, Parkinson's disease and psychotic disorders. Because these inventions are distinct for the reasons given above and the search required for Invention VII is not required for Invention VIII, restriction for

examination purposes as indicated is proper. Moreover, the searches in non-patent literature databases would be extensive and will not overlap thus presenting a search burden to be searched together. Thus, Group VII has been appropriately restricted from Group VIII on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Notice of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

Claims 29-30 are generic to the following patentably distinct species: pathologies selected from the group consisting of depression, Parkinson's disease, and psychotic disorders, and atypical antipsychotic neuroleptics chosen from olanzapine, quetiapine, risperidone, sertindole, or ziprasidone. Because each of the disclosed pathologies encompass different symptamology and the disclosed antipsychotic neuroleptics are patentably distinct, restriction for examination purposes as indicated is proper.

In the event that Applicant elects Group VIII for further prosecution on the merits, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of one pathology selected from depression, Parkinson's disease, and psychotic disorders (enumerated in claim 29), and one atypical antipsychotic neuroleptic (enumerated in claims 30-31) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. Currently claims, 29-31 are generic.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion to Restriction Requirement

Conclusion to Restriction Requirement

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Due to the complex nature of the instant restriction requirement, a written restriction requirement was necessitated. See MPEP § 812.01.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER